Departmental Solicitor's Office

Department of
Finance and
Personnel
www.dfpni.gov.uk

2nd Floor, Centre House
79 Chichester Street
Belfast BT1 4JE
Tel: [redacted]
Fax:
DX464 NR Belfast1

Ms Anne Dillon
The Inquiry into Hyponatraemia-related Deaths
Arthur House
41 Arthur Street
BELFAST
BT1 4GB

RECEIVED
21 FEB 2013
INQ-4071-13

Your Ref: JOH-0047-09
Our Ref: LIT 477/08/CR

Date: 22nd February 2013

Dear Anne

REQUEST FOR DOCUMENTS RE SERIOUS ADVERSE INCIDENT REPORTING

I refer to the above and your request for documents dated 15 February 2013 and attach herewith the circulars which the Department have sourced to date. I understand other material is still being reviewed and should any further relevant documents be located I will return to you immediately.

Yours sincerely

Catherine Rodgers

CATHERINE RODGERS
for The Solicitor
Direct Dial: [redacted]

Encs

INVESTORS IN PEOPLE

DFI/13/127180/CR/J,B

MINISTRY OF HEALTH AND SOCIAL SERVICES
HSS4(OS) Branch
Dundonald House Upper Newtownards Road Belfast BT4 3SF
Telex 74578 Telephone 0232 (Belfast) 650111 ext

The Chief Administrative Officer of
each Health and Social Services Board

Please reply to The Secretary
Your reference

Our reference A1034/73
Circular Ref No HSS4(OS) 1/7
Date 30 October 1973

Dear Sir

NOTIFICATION OF UNTOWARD EVENTS IN PSYCHIATRIC AND SPECIAL CARE HOSPITALS

1. I am writing to draw your attention to a long-standing administrative arrangement whereby the Northern Ireland Hospitals Authority undertook to notify the Ministry of the details of all untoward events involving patients in psychiatric or special care hospitals. Untoward events include

a) unauthorised absences;

b) accidents; and

c) sudden, unexpected or unnatural deaths.

2. It is essential that this practice be continued. Each Health and Social Services Board should therefore arrange for a telephone message to be sent to HSS4(OS) Branch, Dundonald House, Upper Newtownards Road, Belfast BT4 3SF, (telephone Belfast 650111 extension 397) as soon as possible after the occurrence of any such untoward event, with the following information:

a) the nature of the occurrence (ie whether an unauthorised absence, an accident or a sudden, unexpected or unnatural death);

b) a brief description of the circumstances of the event;

c) the name of the patient involved and his hospital status;

d) the name of the hospital of which he was an in-patient and if the incident occurred in any place other than that hospital, the location of the event;

e) the date and time of the occurrence; and

f) whether the patient's relatives, the RUC and the Ministry of Home Affairs, as appropriate, have been informed of the event.

3. To enable the necessary information to be furnished to the Ministry, each Health and Social Services Board should ask the psychiatric and special care hospitals within its area to notify the Board by telephone, in the first place, of the details of an untoward event immediately its occurrence becomes known. Immediate notification is particularly important where a death has occurred.

Yours faithfully

Trusts and Human Resources Directorate

HSS
EXECUTIVE

Chief Executive of each HSS Trust

Chief Executive/General Manager of each
Health and Social Services Board

13 May 1997

Dear Sir/Madam

CIRCULAR HSS (THRD) 1/97 - NOTIFICATION OF UNTOWARD EVENTS IN PSYCHIATRIC & SPECIALIST HOSPITALS FOR PEOPLE WITH LEARNING DISABILITY

The above circular letter was issued on the 12 May and I would now be grateful if you would destroy that copy and replace it with the attached one.

Yours faithfully

John Townson
Deputy Director

Health and Social Services Executive
Dundonald House Upper Newtownards Road Belfast BT4 3SF Northern Ireland Telephone [redacted] Facsimile [redacted]

Trusts and Human Resources Directorate

HSS

Chief Executive of each HSS Trust

Chief Executive/General Manager of each
Health and Social Services Board

13 May 1997

HSS (THRD) 1/97

Dear Sir/Madam

NOTIFICATION OF UNTOWARD EVENTS IN PSYCHIATRIC & SPECIALIST HOSPITALS FOR PEOPLE WITH LEARNING DISABILITY

Circular HSS (OS) 1/73 requires Health and Social Services Boards to notify the Department of any untoward events involving patients in psychiatric or special care hospitals.

Since their establishment it has become the practice for Trusts to notify the Department of such events directly. At the same time untoward events whether occurring in hospital or otherwise are reported to HSS Boards and to the Mental Health Commission for Northern Ireland under separate arrangements.

Following a review of its business areas the HSS Executive has decided that, from receipt of this letter, untoward events should be notified to the Trusts and Human Resources Directorate, Room 605, Dundonald House, telephone (01232) 524955. Serious incidents should be notified by phone in the first instance and all incidents should be reported in writing. Trusts should, of course, continue to follow any requirements placed on them by their commissioning Boards and the Mental Health Commission concerning untoward events.

Yours faithfully

John Townson
Deputy Director

cc. Mr Walsh (Mental Health Commission)

Health and Social Services Executive
Dundonald House Upper Newtownards Road Belfast BT4 3SF Northern Ireland Telephone [redacted] Facsimile [redacted]

HEALTH ESTATES

ADVERSE INCIDENT CENTRE

SAFETY NOTICE

SN(NI)2000/02
DATE: 21 January 2000

For Attention and Action by:
Chief Executive of each HSS Trust
Ceneral Manager/Chief Executive of each HSS Board
Chief Executive of each Agency

TITLE:
UNWIN WHEELCHAIR CLAMPS - IMPROVED USER INSTRUCTIONS

MANUFACTURER/SUPPLIER
Unwin Safety Systems

PROBLEM
Incorrect clamping of a wheelchair in a vehicle allowed it to tip backward, fatally injuring the occupant.

ACTION
Those responsible for the provision of wheelchairs, wheelchair accessories or equipment for the use with wheelchairs in transport, or for the transport of persons in wheelchairs, should ensure that staff and carers are given all relevant up to date safety information, particularly concerning methods of securing wheelchairs in vehicles.

In particular, for Unwin clamping systems, this will include:
- obtaining updated instructions from Unwin Safety Systems
- ensuring that these are provided to transport staff and carers
- ensuring that transport staff are adequately trained in the correct use of clamps including any limitations in their use

Staff and carers should take care:
- to use the correct attachment points on the wheelchair
- that sufficient space is allowed within the vehicle for each wheelchair and occupant, to remove the risk of the occupant coming into contact with other equipment or fixtures in the vehicle.

DISTRIBUTION
This notice should be brought to the attention of all who need to know or be aware of it. This will include:

- Wheelchair Service Managers
- Rehabilitation Engineers (Wheelchairs or Seating)

HEALTH ESTATES

ADVERSE INCIDENT CENTRE

SAFETY NOTICE

DISTRIBUTION (continued)

- Occupational Therapists (involved in wheelchair or seating provision)
- Nursing Staff
- Wheelchair or Seating repair Services
- Safety Liaison Officers
- Risk managers
- Manager of Hospital Transport Services
- Manager of Community Transport Services
- Seating Service Managers
- Portering Service Managers
- Community & Social Services Staff
- Hospices
- Loan Stores
- Supplies Officers
- Trading Standards Officers
- Day Care Services for Elderly or Disabled People

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

BACKGROUND

Unwin clamps fitted to the wheelchair were incorrectly located too close to the rear axle of the wheelchair; this allowed the wheelchair to tip backwards as the vehicle accelerated. The occupant's head contacted the rear door of the vehicle and this resulted in fatal injuries. User instructions were available in the vehicle which showed that the clamps should have been fitted forward of the wheelchair rear axles. Investigation revealed, however, that the instructions did not specify the exact point of fitting to the wheelchair to minimize the risk of tipping. Updated instructions, emphasising the importance of correct positioning of the clamps, can now be obtained form Unwin.

Guidance issued by the Department of Transport, in their document; VSE 87/1 Code of Practice "The Safety of Passengers in Wheelchairs on Buses" gives advice on transporting wheelchair passengers in particular outlines space requirements for wheelchairs within the vehicles.

This safety Notice reinforces earlier guidance given in Safety Acti Notice SAN (NI) 99/47 - Safety of Wheelchair passengers in Vehicles.

HEALTH ESTATES

ADVERSE INCIDENT CENTRE

SAFETY NOTICE

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Mr Phil Millbank
Unwin Safety Systems
Willow House
Artillery Road
Lufton Trading Estate
Yeovil

Tel: [redacted]
Fax:

Enquires to the AIC should quote the reference number SN(NI) 2000/02 be addressed to:

Adverse Incident Centre (AIC)
Health Estates
Estate Policy
Stoney Road
Dundonald
Belfast BT16 1US

Marked for the attention of Mr Brian Godfrey

Tel: [redacted]
Fax:
Email: brian.godfre[redacted]

Brian Godfrey
AIC Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, buildings, estate systems and equipment should be reported to the AIC as soon as possible.

Advice on how to report is given in ----------

Health Estates is an Executive Agency of the Department of Health, Social Services and Public Safety

Estate Policy Directorate
Health Estates

"DOING NO HARM"
THE NORTHERN IRELAND DEFECT & INVESTIGATION CENTRE SAFEGUARDING THE HEALTH OF PATIENTS, STAFF AND CLIENTS

HSS EXECUTIVE

Chief Executive/General Manager
Health and Social Services Boards
Chief Executive
Health and Social Services Trusts
General Manager
Central Services Agency
Chief Executive
Regional Medical Physics Agency
Chief Executive
Northern Ireland Blood Transfusion Service

Our Ref: PEL(00)2

Date: 25 February 2000

Dear Sir/Madam

ADVERSE INCIDENT REPORTING

Summary

The HPSS hold Electro Medical equipment with a replacement value in the order of. £250-£270 Million. It provides a substantial asset that needs to be managed efficiently and safely at the highest level in HPSS organisations to improve the quality of care to patients.

The aim of the Northern Ireland Defect and Investigation Centre (NIDIC) is to safeguard the health of patients, staff and clients.

We are consulting with the HPSS as an integral part of a review of current NIDIC documentation and procedures. Your co-operation is requested in helping us to identify what we can change and improve that will help us in this aim.

Action:

- **Each HPSS organisation should consult with staff who receive warning notices and guidance publications to allow an organisational response to the Review Questionnaire attached.**

Health Estates
Stoney [redacted] Northern Ireland Telephone [redacted] Facsimile [redacted]

- **ONE completed questionnaire reflecting the views of the organisation should be returned to the address provided by 10 March 2000. In practice, the appointment of an organisational co-ordinator for this exercise is recommended.**

Suggested Distribution:

- Officers with responsibility for setting organisational policy for medical device and equipment management.
- Liaison Officers with responsibility for receipt and distribution of Northern Ireland Defect and Investigation Centre warning notices, Device Bulletins, evaluation reports and guidance publications.
- Health & Safety Officers.
- Nurse Executive Directors and Medical Executive Directors

Background:

Analysis of HPSS adverse incident reports to the NIDIC indicates that there is a wide variance between Trusts of similar size and operations in the levels of reported adverse incidents. We are consulting with the HPSS as an integral part of a review of current NIDIC documentation and procedures that will assist HPSS organisations achieve improvement in this area. Your co-operation is requested in helping us to identify what we can change and improve that will help you and us in this aim. This will include:

a. Distribution arrangements in HPSS organisations for Hazard and Safety Action Notices, Device Bulletins and other device management publications;

b. The format and means of distribution of Hazard Notices, Safety Action Notices and Device Bulletins;

c. The procedures in place for reporting adverse incidents.

d. Ensuring that all users of medical equipment are properly trained.

We will be contacting you shortly with details of the results of the consultation exercise and informing you of some of the changes that we intend to implement.

Should you require any further information concerning this letter, please contact;

Mr Brian Godfrey
Manager
NIDIC
Room A11
Health Estates
Stoney Road
Dund .nald, BT16 1US
Telephone: [redacted]
Fax:
E-mail: brian.godfrey[redacted]

Yours faithfully

S BLAYNEY
Director

NIDIC REVIEW
HPSS CONSULTATION QUESTIONAIRE

Instructions for Completion

Each HPSS organisation should consult with staff who receive warning notices and guidance publications to allow an organisational response to the Questionnaire. Suggested distribution for comments are:

- Officers with responsibility for setting organisational policy for medical device and equipment management.
- Liaison Officers with responsibility for receipt and distribution of Northern Ireland Defect and Investigation Centre warning notices, Device Bulletins, evaluation reports and guidance publications.
- Health & Safety Managers, co-ordinators.
- Nurse Executive Directors and Medical Executive Directors

Please include any additional comments that you may have about any of the questions on a separate sheet and return this along with the completed questionaire.

ONE completed questionnaire reflecting the views of the organisation should be returned to:

Mr Brian Godfrey
Manager
NIDIC
Room A11
Health Estates
Stoney Road
Dundonald, BT16 1US

Telephone: [redacted]
Fax:
E-mail:brian.godfrey[redacted]

Please complete the following:

Completed by (Print): _____

Organisation: _____

Signed: _____

Job Title: _____

Date: _____

NIDIC REVIEW
HPSS CONSULTATION QUESTIONAIRE

Ref	Question	Answer
1	Has an Executive Board member been appointed with responsibility for medical equipment management? If Yes, Provide details. (Recommendation in NAO report - **The Management of Medical Equipment in NHS Acute Trusts in England, June 1999**)	
2	Have you in place a device management procedure that includes policies for the purchase, acceptance, maintenance, repair, monitoring and replacement of devices and for the training of users?	
3	Does your organisation have a management policy in place for the distribution of NIDIC warning notices, device management publications and reporting adverse incidents?	
4	Do you have a liaison officer appointed with responsibility for receipt and distribution of NIDIC notices and device management publications? Please provide : Name Address Position Telephone Number Fax Number e-mail address	
5	Hazard Notices, Device Alerts, Safety Action Notices and Device Bulletins are addressed to CEOs. Who decides their onward distribution in your organisation and what criteria are used?	
6	Do you confirm that NIDIC Notices have been received and actioned by the appropriate department?	
7	A new draft format of Notice is attached to the questionnaire. Does this format of Notice make it clear what the problem is and what to do about it? If not, what can be done to improve this? **Please note that the notice is provided in the normal format of double sided A4. If it would be better for you to receive this in single sided A4 format to allow for copying, please indicate your preference.**	
8	Do you have a means of informing the staff in your organisation that publications such as Device Bulletins and Evaluation reports are available?	
9	If NIDIC Notices were distributed by Fax, would this be acceptable to your organisation?	

NIDIC REVIEW
HPSS CONSULTATION QUESTIONAIRE

Ref	Question	Answer
	(Please note that the present colour coding would no longer apply)	
10	If NIDIC Notices were distributed by e-mail, would this be acceptable to your organisation? Would you have any preference over fax or e-mail? (e-mail would require that the recipient checks for receipt daily and actions immediately)	
11	Hazard Notices and Safety Action Notices are currently issued in Red and Blue colour coded paper respectively. If the new draft format of Notice were acceptable, would the present colour coding be necessary?	
12	Device Bulletins are currently issued on yellow colour coded paper with an additional plain paper copy to enable photocopying for organisational use. Should this system continue or should the Device Bulletins be issued in plain paper form only? (Future Device Bulletins may be inclusive of NI requirements and would be produced by the MDA in bound format for issue, preventing the present colour coding to be applied)	
13	Can you suggest any way that NIDIC Notices could be improved?	

NIDIC REVIEW
HPSS CONSULTATION QUESTIONAIRE

Ref	Question	Answer
14	Device Bulletins such as the **Re-Use of Single Use Medical Equipment (DB9501)** have important implications for both users and patients. How was the recommendations contained in this Device Bulletin implemented in your organisations?	
15	Device Management publications such as **"The Management of Infusion Systems"** recommend that users should be provided with appropriate training. How is this recommended training implemented in your organisation?	

SN (NI) 2002/01
DATE: 2 JANUARY 2002

For Attention and Action by:
Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
Chief Executive of each Agency

HEALTH ESTATES

ESTATE POLICY

NORTHERN IRELAND ADVERSE INCIDENT CENTRE

SAFETY NOTICE

TITLE:
REPORTING ADVERSE INCIDENTS AND DISSEMINATING WARNING NOTICES RELATING TO MEDICAL DEVICES, NON-MEDICAL EQUIPMENT, BUILDINGS, AND PLANT

SUMMARY
General Managers and Chief Executives are responsible for ensuring prompt reporting of adverse incidents. This Safety Notice provides information on:

- The Northern Ireland Adverse Incident Centre (NIAIC) adverse incident reporting system;
- Encourages the reporting of adverse incidents involving medical devices, non-medical equipment, buildings and plant;
- and provides information on the dissemination of NIAIC warning notices.

The text of this notice updates and replaces SN(NI)2001/01.

DISTRIBUTION

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- Liaison Officers for onward distribution to all relevant staff including:
- Risk Managers
- Health & Safety Officers/Advisors
- Medical Directors
- Clinical Directors
- Nursing Directors
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- General Medical Practitioners
- General Dental Practitioners
- Opticians
- Community Pharmacists
- Professions Allied to Medicine
- Social Care Staff
- Community Care Staff
- Trust Pharmacists
- Residential & Nursing Homes
- Private Clinics
- Trust Pharmacy Managers

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

HEALTH ESTATES

ESTATE POLICY

NORTHERN IRELAND ADVERSE INCIDENT CENTRE

SAFETY NOTICE

ACTION

The following actions should be taken:

- establish and maintain procedures to ensure the prompt reporting of adverse incidents relating to medical devices, non-medical equipment, buildings and plant to NIAIC in accordance with this notice;
- If they have not already done so, HPSS organisations should nominate a Liaison Officer to co-ordinate the reporting of incidents and the local dissemination of NIAIC warning notices and other guidance material;
- regularly review these procedures and update as necessary.

Further guidance is provided in the Annexes to this Notice. The full text of this Notice and forms for reporting adverse incidents are available from NIAIC's website:
http://www.dhsspsni.gov.uk/hea/niaic

BACKGROUND

The Health Estates Health & Social Services Agency (Health Estates) is an Executive Agency of the Department of Health, Social Services and Public Safety. The aim of the NIAIC, part of Health Estates, is to take all reasonable steps to protect the health of patients, staff and clients. One way in which we aim to achieve this is by investigating reports of adverse incidents involving medical devices, non-medical equipment, plant and buildings. See Annex A and B for a list of examples of medical devices, non-medcial equipment, plant and buildings.

Where the results of investigations, or other information is received, has implications for patients, staff, clients or users, NIAIC issues a Hazard Notice, Advice Notice or Safety Notice advising of hazardous products or unsafe procedures.

WHAT IS AN ADVERSE INCIDENT?

An adverse incident is an event which causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients, staff, clients or other persons. Every Health & Personal Social Services employee has a duty to see that all safety related incidents and potentially harmful products are reported, even on suspicion. For example, adverse incidents may arise due to:

- *shortcomings in the design or manufacture of the medical device, non-medical equipment, plant or building item;*
- *inadequate instructions for use;*
- *inadequate servicing and maintenance;*
- *locally initiated modifications or adjustments*
- *inappropriate user practices, (which may in turn result from inadequate training);*
- *inappropriate management procedures;*
- *the environment in which it is used or stored;*
- *selection of the incorrect type of device for the purpose**

Conditions of use may also give rise to adverse incidents, e.g.:

- *environmental conditions (e.g. electromagnetic interference)*
- *location (e.g. devices designed for hospitals may not be suitable for use in the Community or ambulances).*

* This would not apply to non-medical equipment, plant and buildings.

HEALTH ESTATES

ESTATE POLICY

NORTHERN IRELAND ADVERSE INCIDENT CENTRE

SAFETY NOTICE

WHAT TO REPORT

An adverse incident should be reported to NIAIC if the incident has led to, or were it to occur again could lead to:

- *death, life-threatening illness or injury;*
- *deterioration in health;*
- *the necessity for medical or surgical intervention;*
- *unreliable test results leading to inappropriate diagnosis or therapy.*

NIAIC should also be informed of any other related adverse incidents or minor faults and discrepancies, since they may take on a greater significance when aggregated with other similar events in demonstrating trends or may be indicators of inadequate quality assurance on the part of the manufacturer or supplier.

NIAIC should be informed of adverse incidents even if they appear to be caused by human error as:

- *the error may be partly (or wholly) due to deficiencies in the design of the device, non-medical equipment, plant or building item or instructions for their use;*
- *it will help prevent repetition of the same mistake, possibly by promulgating advice or improving the design of future devices, non-medical equipment, plant and building items.*

NIAIC is concerned with preventing adverse incidents occurring, not with assigning blame or liability.

ADVERSE INCIDENT REPORTING PROCEDURES

All staff who work in Health and Personal Social Services, including contractors and those in the Private Sector, should be regularly reminded of their responsibilities with regard to adverse incident reporting and of the relevant local procedures including the need to isolate and retain defective or suspect items. This information should also be conveyed to new and agency staff as part of their induction training.

The procedures should ensure that:

- *where appropriate, a liaison officer is appointed in each HPSS organisation with the necessary authority to take responsibility for the reporting of adverse incidents to NIAIC as detailed in Annex C to this notice and that NIAIC is informed of any changes to liaison officer contact details when they occur;*
- *devices/equipment or plant involved in an adverse incident together with other material evidence (e.g. packaging of a single use device, giving sets used with infusion pumps etc.) should be clearly identified and kept in quarantine, where practicable, until NIAIC's investigating officers have been consulted. Where quarantine is not practicable, the state of the device(s) at the time of the incident should be recorded for use in any subsequent investigation. Please refer to Annex D for further detail;*
- *local action is taken as necessary to ensure the safety of patients, staff, client and others, .*

Regular reviews should be undertaken to ensure that the procedures are effective and are being followed.

HEALTH ESTATES

ESTATE POLICY

NORTHERN IRELAND ADVERSE INCIDENT CENTRE

SAFETY NOTICE

HOW TO REPORT AN INCIDENT

Adverse Incidents should be reported to NIAIC as soon as possible by completing an Adverse Incident Report Form (Annex F gives an example of Report Form A1). Serious cases should be reported to NIAIC by the fastest means available e.g. telephone fax or e-mail. Telephone reports should be followed up as soon as possible by completing an Adverse Incident Report Form. A new online reporting facility will shortly be available on the NIAIC website. This is our preferred method of receiving reports.

The initial report of an incident should contain as much relevant detail including information about any device or equipment involved such as the manufacturer and supplier names, addresses and telephone numbers, product names and serial numbers etc. Having this information available allows us to begin the investigation immediately. Names and contact details of persons who may be contacted for further information should be included. Forms for reporting incidents are available from the NIAIC website in MS Word and PDF format or may be obtained by contacting NIAIC at the address provided.

Outside normal office hours, the Department's Duty Officer can be contacted at Stormont House telephone 02890 520700 giving an indication that the report is for the NIAIC, Health Estates. Otherwise, if a case is less serious it should be reported on the next working day.

General Information on how NIAIC deals with received incident reports, the investigation process, including manufacturer's legal responsibilities and the criteria for the various levels of warning notice are given in Annex E.

REPORTING TO OTHER ORGANISATIONS INVOLVED WITH ADVERSE INCIDENTS

Please report adverse incidents to the appropriate organisation. **All those involving medical device, non-medical equipment, plant or building items should be reported to NIAIC.**

This reporting system does not affect the statutory or other duties of staff locally to take appropriate actions as required legally and/or by line management, as a result of an adverse incident. These include:

- *to safeguard patients, staff, clients and others*
- *to prevent further use of a product which may be defective*

As part of the above actions, Regional Supplies Service may issue their own notices, which identify problems and are used to bring them to the attention of users. These Notices should not be confused with NIAIC's Hazard, Advice and Safety Notices.

RIDDOR

Incidents involving certain types of injury, occupational disease or dangerous occurance, whether involving medical devices, non-medical equipment, buildings or plant or not, are legally notifiable to the Health & Safety Executive under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (Northern Ireland) 1997 (RIDDOR), and the Ionising Radiation Regulations

(Northern Ireland) 2000.

Notification to NIAIC does not count as, or substitute for, any other report, which should be sent (e.g., in respect of an employee's industrial injury).

MEDICINES

Incidents involving medicines should be reported to Pharmaceutical Branch of the Department of Health, Social Services and Public Safety.

FOOD

Incidents relating to foods involving contamination or potential contamination should be reported immediately to the local environment health officer (EHO) who will decide on what, if any, further action will be taken.The EHO will also report the incident to the Food Standards Agency as necessary.

Enquires to NIAIC about this notice should quote the reference number SN (NI) 2002/01 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Estate Policy Admin
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: [redacted]
Fax:
Email: NIAIC[redacted]

Brian Godfrey
NIAIC Manager

Health Estates is an Executive Agency of the Department of Health, Social Services and Public Safety

Áisíneacht Feidhmeannach don Roinn Sláinte, Seirbhísí Sóisialta agus Sábháilteacht Phoiblí

HEALTH ESTATES

ESTATE POLICY

NORTHERN IRELAND ADVERSE INCIDENT CENTRE

SAFETY NOTICE

ANNEX A

ADVERSE INCIDENT REPORTS CONCERNING MEDICAL DEVICES AND EQUIPMENT

The following list provides some examples of medical devices. It is not a comprehensive list and is provided for guidance only.

- Medical Devices and equipment for the diagnosis or treatment of disease, or monitoring of patients e.g.: non-medicated dressings; surgical instruments and equipment; IV administration sets and pumps; anaesthetic equipment; powered implants (e.g. pacemakers); implantable defibrillators; radiotherapy equipment (brachytherapy, external beam); ophthalmic equipment; sphygmomanometers; vaginal speculae; examination gloves; catheters (e.g. urinary, cardiac); endoscopes; patient monitoring equipment (e.g. cardiac monitors); surgical implants (e.g. orthopaedic prostheses, bone cements, heart valves); x-ray systems, ultrasound imagers and CT/MR scanners; dental equipment and materials; chiropody equipment; thermometers; physiotherapy equipment; syringes and needles; blood warming cabinets.

- Medical Devices and equipment for critical care, e.g.: ventilators; defibrillators.

- Medical Devices and equipment used in the care of patients, e.g.: wheelchairs and special support seating; walking aids; patient hoists; orthotic and prosthetic appliances; pressure relief equipment.

- Medical Devices and equipment used by ambulance services, e.g.: stretchers and trolleys; resuscitators

- Medical Devices and equipment for daily living, e.g.: commodes, urine drainage systems; incontinence products; hearing aids; domiciliary oxygen therapy systems; prescribable footwear; bathing and showering equipment; special chairs.

Medical devices and equipment also include the following:

- *In-vitro* diagnostic medical devices and their accessories, e.g.: devices for blood glucose measurement; pregnancy test kits; urine test strips; hepatitis and HIV test kits; blood gas analysers; specimen collection tubes.

- intra-uterine devices (IUDs); contact lenses and care products; condoms.

We are also interested in products which, whilst not themselves medical devices, are used closely in conjunction with these devices, e.g.: blood and tissue storage systems; disinfecting and sterilizing equipment e.g. bench top sterilizers; chemical and biological indicators used in sterilization processes.

Medical devices do not include general workshop equipment such as power or machine tools.

Some equipment is designed to be permanently connected to installed services, e.g. medical gas pipework, ducting or electrical supply. In these cases, the device should be regarded as comprising all parts up to and including the means of connection to the installed service.

ANNEX B

ADVERSE INCIDENT REPORTS CONCERNING NON-MEDICAL EQUIPMENT, PLANT AND BUILDINGS

The following list provides some examples of non-medical equipment, plant and building fabric that we are interested in:

- Engineering plant and services of all types e.g. boilers, generators, heating, ventilation, water, drainage, and electrical installations and any other fixed plant.
- Fire Protection installations and equipment.
- Permanently installed sterilizers, bedpan washers and disposal units.
- Equipment in laundries, catering departments, workshops and any plant or equipment used for maintenance or cleaning.
- Piped medical gas and vacuum installations, Vacuum Insulated Evaporators (VIE) and anaesthetic gas scavenging systems.
- Fixed luminaires, including operating and examination lamps
- Communications equipment e.g. telephone, nurse call, paging, alarms and radio.
- Lightning protection and anti-static precautions.
- Built environmental aspects of COSHH
- Installation aspects of fume cupboards and microbiological safety cabinets, including ductwork and their interaction with ventilation systems.
- Buildings and building components and plant used in maintenance and construction.
- Ambulances but excluding motor vehicles such as those for disabled persons and lease hire and goods vehicles.

ANNEX C

ROLE OF LIAISON OFFICERS

Each HPSS organisation has now nominated a liaison officer. If you need to let us know about a change in liaison officer details e.g. name, address, phone, fax numbers and e-mail address, please contact us at telephone number 02890 523704; fax: 02890 523900, e-mail: NIAIC@dhsspsni.gov.uk.

Reporting Adverse Incidents

Guidance for establishing procedures for reporting adverse incidents to NIAIC is outlined in this Notice. Local procedures for adverse incident reporting should also ensure that relevant local staff are kept informed of any adverse incidents e.g. by copying any report made to NIAIC to relevant staff or forwarding all reports to NIAIC via the Liaison Officer. This is the preferred procedure as it allows the HPSS organisation to demonstrate compliance with Health & Safety legislation by having a record of all reports of adverse incidents. A sample staff information sheet is provided at Annex G.

Dissemination of NIAIC warning notices (Hazard Notices, Advice Notices and Safety Notices)

A complete record of advice and recommendations issued by NIAIC should be maintained by each HPSS organisation. Warning notices should be distributed to the appropriate people in the organisation and recommendations contained within implemented.

One colour-coded copy (PINK for Hazard Notice, WHITE for Advice Notice and BLUE for Safety Notice) is sent by first class post to the Chief Executive/General Manager and the Liaison Officer in all HPSS organisations. Hazard Notices & Advice Notices are faxed in advance to Liaison Officers. Liaison Officers also receive all warning notices by e-mail (Notices will be in MS Word format).

Warning notices concerning High Voltage equipment will be distributed to HPSS Trusts that have HV switchgear only. This will ensure that all warning notices are relevant to the organisations concerned.

There may be occasions when the warning notice refers to a medical device, non-medical equipment, plant or building item that users do not use. When a safety related concern arises, NIAIC's priority is to alert all potential users of the particular device, equipment, plant or building item. This includes professionals who do not use the medical device or item of equipment, but have contact with members of the public that may. In the interests of patient, staff and client safety it is vital that each warning notice received is checked and acted upon as necessary.

Organisations should:

- identify a fax number and e-mail address for the primary receipt of Hazard Notices and Advice Notices;
- arrange for someone to deputise in the Liaison Officer's absence;
- establish procedures to record action taken following the receipt of warning notices indicating to whom they have been sent;
- develop procedures to ensure that new staff are made aware of recent warning notices, Device Bulletins or Guidance Booklets (for example: establish the procedure in codes of practice wherever possible; set up a folder of warning notices; establish an electronic library of warning notices etc.)

- distribute Hazard Notices and Advice Notices immediately. Safety Notices could take a less immediate route depending on the subject and the local situation;
- ensure that each Hazard Notice, Advice Notice and Safety Notice is distributed individually. Do not accumulate and staple warning notices together;
- target Hazard Notices, Advice Notices and Safety Notices to the appropriate recipient identified on each notice and is brought to the attention of all who need to know or be aware of it in accordance with local procedures. We recommend that you identify a candidate recipient in each relevant area for your organisation and the procedures for reaching;
- maintain records to show (for example):
  1. date issued;
  2. signed assurance from recipient that required action has been taken (for example – appropriate staff have been made aware of the Notice);
- do not cut and paste text from any NIAIC Warning Notice (this could change the context of the message).

Dissemination of NIAIC Device Bulletins, Guidance Booklets and Evaluation Reports

Device Bulletins are issued when guidance and information is needed over an extended area, for example, decontaminating endoscopes. They deal effectively with problems which keep recurring and which can be solved by good training and practice, rather than by modifying or withdrawing a particular product. It is vital that they are issued to all staff with responsibility for training, staff responsible for setting organisational policies for equipment management and any other relevant staff.

Guidance Booklets are produced occasionally when guidance is needed for topical issues and a Device Bulletin would not be a suitable format. Their distribution is outlined in the publication.

Device Bulletins and Guidance Booklets are produced in printed form. NIAIC will distribute an agreed number to each Liaison Officer for distribution within their organisation. HSS Board Liaison Officers are additionally responsible for ensuring that Registration and Inspection Units distribute to Residential and Nursing Homes and Private Clinics when the publication is relevant to these areas. NIAIC will arrange for distribution to General Medical Practitioners, General Dental Practitioners, Opticians and Community Pharmacists.

Equipment Evaluation Reports, Disability Equipment Assessments and Pressure Sore Prevention Reports should be made available to staff responsible for equipment purchasing in these specific areas.

ANNEX D

DEFECTIVE OR CONTAMINATED ITEMS AND EVIDENCE

Defective Items

Defective items should not be repaired (either in-house or by a third party), returned to the manufacturer/supplier or discarded before an investigation has been carried out. The manufacturer or supplier should be informed promptly, and allowed to inspect the items if accompanied by an appropriate person. To facilitate an investigation, it may be possible to provide the manufacturer with a sample(s) of unused stock from a large batch. However, the manufacturer must not be allowed to exchange, interfere with, or remove any part of the product implicated in the incident if this would prejudice NIAIC investigations, or those of other official bodies.

If medical devices or other equipment are required to be kept in use, where possible remove defective parts so that the equipment may be repaired for re-use. Any parts so removed must be quarantined and securely stored pending investigation. NIAIC's advice should be sought and, in all cases, the defective parts should be clearly identified and kept secure. If it is not possible to remove defective parts or withdraw the machine from use, staff should be made aware of the need for increased vigilance and extra caution during use (see Evidence below).

Contaminated Items

Advice on procedures to be followed if healthcare equipment is contaminated and constitutes a biohazard is contained in PEL(94)34 and SAN(NI) 95/24. NIAIC can provide advice where necessary, particularly on whether arrangements should be made for the item to be examined prior to any decontamination.

Where decontamination/cleaning would destroy vital evidence, the item should be placed in protective containment, labelled and placed in quarantine. NIAIC and the manufacturer/supplier should be contacted for advice prior to any further action being taken.

IT IS ILLEGAL TO SEND CONTAMINATED ITEMS THROUGH THE POST

Evidence

All material evidence should be labelled and kept secure under the charge of a responsible officer. This includes the products themselves and, where appropriate, packaging material or other means of batch identification. The evidence should not be interfered with in any way except for safety reasons or to prevent its loss. If necessary, a record should be made of all readings, settings and positions of switches, valves, dials, gauges and indicators, together with any photographic evidence and eyewitness reports.

ANNEX E

INVESTIGATION OF ADVERSE INCIDENTS

INITIAL ACTION

When a report is received by NIAIC:

- It is logged on to the NIAIC database;
- an acknowledgement is sent to the reporter; and
- senior management are alerted if a fatality is involved
- If the report concerned a Medical Device, the Medical Devices Agency (MDA) are contacted to determine if similar incidents have been reported

The report is passed to one of NIAIC Investigation Officers to review the report and decide on the most appropriate method of investigation.

INVESTIGATION

In the course of an investigation, staff may:

- talk with the user and manufacturer;
- visit the site of the incident when necessary;
- review evidence; and
- if appropriate, issue safety advice to the HPSS.
- notify the MDA of investigation outcomes for incidents involving medical devices and NHS Estates for incidents involving non-medical equipment, plant and buildings.

LEGAL RESPONSIBILITIES OF MEDICAL DEVICE MANUFACTURERS

As a result of UK Medical Device Regulations implementing the EC Medical Devices Directives concerning medical devices, manufacturers of medical devices are required by law to report to the UK Competent Authority (Medical Devices Agency) certain incidents involving their products. This system is known as the 'Vigilance System' and it covers incidents which have led to, or which might have led to, death or serious deterioration in health and/or product recall.

For the majority of adverse incidents reported to NIAIC, the manufacturer is provided with information about the incident, where it occurred and the device involved. The manufacturer takes responsibility for resolving the incident but NIAIC monitors progress and reviews the manufacturer's response. If an adverse incident involved death or serious injury, or the potential to do so is high, NIAIC may ask MDA to take the lead on the investigation.

An investigation is re-appraised if new information comes to light. Outcomes of investigations are reviewed in order to identify patterns or clusters of incidents, which may require possible further investigation.

NIAIC REPORT

On investigation completion, NIAIC investigation officers will review the information available and provide the reporter of the incident with a report.

TYPES OF WARNING NOTICE ISSUED

Where necessary, NIAIC will issue advice in the form of warning notices. The criteria for the various warning notices, in broad terms, are as follows:

Hazard Notices are issued: -

- in cases of actual death or serious injury, or when death or serious injury would have occurred, but for fortuitous circumstances or the timely intervention of health care staff or a carer, and
- where the medical device, non-medical equipment, plant or building item is clearly implicated, and
- where immediate action is necessary to prevent recurrence.

Advice Notices are issued: -

- in cases where there is the potential for death or serious injury, or there may be implications arising from long term use, and
- where the medical device, non-medical equipment, plant or building item is likely to be implicated, and
- where the recipient is expected to take immediate action on the advice.

Safety Notices are used to recommend or inform: -

- where action by the recipient will improve safety,
- where it is necessary to repeat warnings on long standing problems,
- to support or follow up manufacturers' field modifications.

Professional Officer Letters are issued: -

- by the Chief Officer in any of the professional disciplines, e.g. Medical, Nursing, Pharmaceutical, Dental, etc. They are normally used when improper use or misuse of equipment has contributed to an occurrence.

Please note that Hazard Notices and Advice Notices specify immediate actions and it is extremely important that all personnel are instructed in the proper procedures for dealing with safety information and reporting of adverse incidents.

ANNEX G

NORTHERN IRELAND ADVERSE INCIDENT CENTRE

HEALTH ESTATES
ESTATE POLICY

IF AN INCIDENT HAPPENS:

Report the incident if it has led to, or were it to occur again could lead to:

- **death, life-threatening illness or injury;**
- **deterioration in health;**
- **the necessity for medical or surgical intervention;**
- **unreliable test results leading to inappropriate diagnosis or therapy.**

Also report:

- **any other related adverse incidents or minor faults and discrepancies.**
- **adverse incidents even if they appear to be caused by human error.**

What to do:

- **Keep devices/equipment or plant involved in an adverse incident together with other material evidence (e.g. packaging, giving sets used with infusion pumps etc.) clearly identify them and keep in quarantine.**
- **If this is not practicable, record the state of the device(s) at the time of the incident.**
- **Take any local action as necessary to ensure the safety of patients, staff and clients.**

Who to Contact:

- **Liaison Officer for your organisation:**

  Telephone:

- **Northern Ireland Adverse Incident Centre (NIAIC)**
  Health Estates
  Estate Policy Directorate
  Stoney Road
  Dundonald BT16 1US **Telephone** [redacted]
  Fax
  e-mail **NIAIC** [redacted]